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TITLE: Slippery, tenaciously adhering hydrogel coatings containing a polyurethane-urea polymer hydrogel commingled with a poly(N-vinylpyrrolidone) polymer hydrogel, coated polymer and metal substrate materials, and coated medical devices

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CLAIMS:

We claim:

1. A material bearing thereon a coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea polymer hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel, said material and coating comprising:

- a hydrophilic or hydrophilicized hydrophobic polymer substrate or a metal substrate, having a surface with reactive chemical functional groups thereon, at least some of which are amine-containing groups;
- a first coating, applied onto said substrate surface, said first coating being a hydrophilic polyurethane-urea prepolymer intermediate, that is capable of forming a polyurethane-polyurea hydrogel-forming polymer, and that contains terminal isocyanate groups that are free to react with other species, such that at least some of said terminal isocyanate groups are reacted with and are covalently bonded to said reactive chemical functional groups on said substrate surface, forming covalent polyurea bonds therewith, resulting in the formation of a tie coat of a polyurethane-polyurea hydrogel-forming polymer, on said substrate surface, such that said polyurethane-polyurea hydrogel-forming polymer tenaciously adheres to said substrate surface; and wherein at least some of said terminal isocyanate groups of said polyurethane-urea prepolymer intermediate are present in said polyurethane-polyurea hydrogel-forming polymer such that they remain free to react with other species; and
- a second coating, applied onto said tie coat, said second coating being an aqueous solution of a poly(N-vinylpyrrolidone) hydrogel-forming polymer, such that a barrier coat which is a commingled hydrogel of a polyurethane-polyurea polymer hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel is formed wherein water of said aqueous solution of said poly(N-vinylpyrrolidone)

hydrogel-forming polymer is bound with said polyurethane-polyurea hydrogel-forming polymer to form a polyurethane-polyurea polymer hydrogel;
wherein water of said aqueous solution of said poly(N-vinylpyrrolidone) hydrogel-forming polymer is bound with said poly(N-vinylpyrrolidone) hydrogel-forming polymer to form a poly(N-vinylpyrrolidone) polymer hydrogel; and
wherein said poly(N-vinylpyrrolidone) polymer hydrogel is adherent to said substrate surface as a result of being commingled with said polyurethane-polyurea polymer hydrogel.

2. The material according to claim 1 wherein said polymer substrate is a plastic or a rubber.

3. The material according to claim 2 wherein said polymer substrate is selected from the group consisting of thermoplastic polyurethanes (TPU)'s, polyesters, nylon polymers, block copolymers of a polyether polymer and a polyester polymer, and block copolymers of a polyether polyol and one selected from the group consisting of polyamides, polyimides, polyolefins, synthetic hydrocarbon elastomers, and natural rubber.

4. The material according to claim 3 wherein said polyester is polyethylene terephthalate (PET).

5. The material according to claim 3 wherein said nylon polymers include nylon-11 and nylon-12.

6. The material according to claim 3 wherein said polyolefins include polyethylenes (PE) and polypropylenes (PP).

7. The material according to claim 3 wherein said polyether polymer is aliphatic and said polyester polymer is aromatic.

8. The material according to claim 1 wherein when said substrate is a polymer, said reactive chemical functional groups are selected from the group consisting of amine-containing groups, hydroxyl groups, carboxyl groups, carbonyl groups, and combinations thereof.

9. The material according to claim 8 wherein said amine-containing groups are selected from the group consisting of amino groups, amido groups, urethane groups, urea groups, and combinations thereof.

10. The material according to claim 9 wherein said amino groups are selected from the group consisting of primary amino groups, secondary amino groups, and combinations thereof.

11. The material according to claim 9 wherein said amine-containing groups are derived from a nitrogen-containing gas selected from the group consisting of ammonia, organic amines, nitrous oxide, nitrogen, and combinations thereof.

12. The material according to claim 11 wherein said organic amines include primary and secondary organic amines, and combinations thereof.

13. The material according to claim 12 wherein said organic amines are selected from the group consisting of methylamine, dimethylamine, ethylamine, diethylamine, n-propylamine, allylamine, isopropylamine, n-butylamine, n-butylmethylamine, n-amylamine, n-hexylamine, 2-ethylhexylamine, ethylenediamine, 1,4-butanediamine, 1,6-hexanediamine, cyclohexylamine, N-methylcyclohexylamine, and ethyleneimine.

14. The material according to claim 12 wherein said organic amines are low boiling primary and secondary organic amines having a structure selected from the group (I-III) consisting of:

R.sub.1 NH.sub.2 I.,

R.sub.1 NHR.sub.2 II.,

and

H.sub.2 NR.sub.3 NH.sub.2 III.,

wherein R.sub.1 and R.sub.2 are monovalent hydrocarbon radicals having from 1 to about 8 carbon atoms; and R.sub.3 is a divalent hydrocarbon radical having from 2 to about 8 carbon atoms.

15. The material according to claim 1 wherein when said substrate is a polymer, said reactive chemical functional groups are affixed to said surface of said substrate by plasma fixation.

16. The material according to claim 1 wherein when said substrate is a polymer that is non-polar or only slightly polar, and hydrophobic, said substrate is first made polar or more polar, and hydrophilic, by attaching polarizing and hydrophilicizing groups selected from the group consisting of hydroxyl groups, carboxyl groups, and carbonyl groups, to the surface of said substrate, before said reactive chemical functional groups are affixed to said substrate surface.

17. The material according to claim 1 wherein said metal substrate is selected from the group consisting of stainless steel, titanium, alloys of steel, nickel, titanium, molybdenum, cobalt, and chromium, and nitinol (nickel-titanium alloy), and vitallium (cobalt-chromium alloy).

18. The material according to claim 1 wherein when said substrate is a metal, said reactive chemical functional groups include amino-silane groups.

19. The material according to claim 18 wherein amino-silane groups have amino terminal groups at one end and silane terminal groups at an opposite end, such that said silane terminal groups are attached to said metal substrate and said amino groups are free to react with other species.

20. The material according to claim 19 wherein lower alkyl groups having from 2 to about 8 carbons are positioned between said silane terminal groups and said amino terminal groups.

21. The material according to claim 18 wherein said amino-silane groups are derived from a compound selected from the group consisting of .gamma.-aminopropyltriethoxysilane, .gamma.-aminopropyltrimethoxysilane, .beta.-aminoethyl-.gamma.-aminopropyltrimethoxysilane, and a prehydrolyzed aminoalkyl silanol, with which said substrate surface is chemically treated.

22. The material according to claim 1 wherein when said substrate is a metal, said reactive chemical functional groups are affixed to the surface of said substrate by chemical treatment thereof.

23. The material according to claim 1 wherein said hydrophilic polyurethane-polyurea prepolymer intermediate is a derivative of a water-soluble polyether polyol and an organic polyisocyanate.

24. The material according to claim 23 wherein said polyether polyol is a copolyether polyol of ethylene oxide and propylene oxide, and said organic polyisocyanate is an isocyanate containing aliphatically bound terminal isocyanate (NCO) groups.

25. The material according to claim 24 wherein said organic polyisocyanate is selected from the group consisting of aliphatic, cycloaliphatic, araliphatic, aromatic and heterocyclic polyisocyanates.

26. The material according to claim 25 wherein said aliphatic, cycloaliphatic, araliphatic, aromatic or heterocyclic polyisocyanate is a diisocyanate or a derivative thereof.

27. The material according to claim 26 wherein said polyisocyanate is selected from the group consisting of 1,6-hexamethylene diisocyanate (HDI), the trifunctional biuret and carbodiimide derivatives thereof, isophorone diisocyanate (IPDI), benzophenone, isomer mixtures of methylene bis(4-cyclohexylene diisocyanates), m-xylylene diisocyanate, m-tetramethylxylylene diisocyanate, p-tetramethylxylylene diisocyanate, and isomer mixtures of bis(isocyanatomethyl) 1,3-cyclohexylene and trans 1,4-cyclohexylene diisocyanate.

28. The material according to claim 25 wherein said organic polyisocyanate is a prepolymer reaction product of a compound selected from the group consisting of water-soluble, hydrophilic mono- and polyfunctional polyethers, polyether alcohols, polyetherpolyols, copolyethers, copolyetheralcohols, copolyether polyols, a block copolyether of a 1,2-alkylene oxide, and a copolyether of a 1,2-alkylene oxide and tetrahydrofuran or tetrahydropropane; and an organic polyisocyanate selected from the group consisting of aliphatic, cycloaliphatic, araliphatic, aromatic, and heterocyclic polyisocyanates and derivatives thereof.

29. The material according to claim 28 wherein said polyether, polyether alcohol, copolyether or copolyether alcohol is a compound selected from the group consisting of water-soluble homopolyethers, homopolyether alcohols, homopolyether polyols of ethylene oxide, copolyethers, copolyether alcohols, copolyether polyols of ethylene and propylene oxides, copolyethers of ethylene and 1,2-butylene oxide, 1,2-alkylene oxide polyethers, copolyethers of mixtures of 1,2-alkylene oxides, and copolyethers of ethylene oxide and tetrahydrofuran.

30. The material according to claim 29 wherein said polyether, polyether alcohol, polyether polyol, copolyether alcohol or copolyether polyol is a compound selected from the group consisting of homopolyethers or homopolyether alcohols of ethylene oxide; and copolyethers or copolyether alcohols of ethylene oxide in an amount of from about 70 to about 85% by weight, and propylene oxide in an amount of from about 15 to about 30% by

weight.

31. The material according to claim 30 wherein said copolymer of ethylene oxide and propylene oxide contains from about 17.5 to about 30% by weight of propylene oxide.

32. The material according to claim 31 wherein said polyether alcohol, polyether polyol, copolyether alcohol, or copolyether polyol has an equivalent weight per hydroxyl group of from about 500 to about 20,000.

33. The material according to claim 32 wherein the equivalent weight per hydroxyl group is from about 2,000 to about 10,000.

34. The material according to claim 33 wherein the equivalent weight per hydroxyl group is from about 3,500 to about 6,000.

35. The material according to claim 32 wherein said polyether polyol or said copolyether polyol is, respectively, a polyether diol, or a copolyether diol, having an equivalent weight of from about 750 to about 5,000.

36. The material according to claim 35 wherein the equivalent weight is from about 1,000 to about 4,000.

37. The material according to claim 29 wherein said 1,2-alkylene oxide polyethers and copolyethers of mixtures of 1,2-alkylene oxides have an equivalent weight of from about 1,500 to about 7,500.

38. The material according to claim 37 wherein the equivalent weight is from about 1,500 to about 2,500.

39. The material according to claim 28 wherein said hydrophilic polyether is moisture free.

40. The material according to claim 28 wherein said hydrophilic polyether further contains an antioxidant.

41. The material according to claim 1 wherein said terminal isocyanate groups of said hydrophilic polyurethane prepolymer intermediate are aliphatically bound to said hydrophilic polyurethane prepolymer intermediate.

42. The material according to claim 1 wherein said coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a polyurethane-polyurea polymer hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel forms a composition selected from the group consisting of an interpolymer hydrogel network, a graft polymer hydrogel, an association polymer hydrogel, and combinations thereof.

43. The material according to claim 1 wherein said moisture-containing, hydrogel-forming compound of said second coating is water.

44. The material according to claim 1 wherein said isocyanate-reactive functional groups of said moisture-containing, hydrogel-forming compound are hydroxyl groups.

45. The material according to claim 1 wherein said coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a polyurethane-polyurea polymer hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel further contains a slip additive.

46. The material according to claim 1 wherein said coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea polymer hydrogel, and a poly(N-vinylpyrrolidone) polymer hydrogel, has a thickness of from about 0.1 mil to about 5 mils.

47. The material according to claim 1 wherein said coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea polymer hydrogel, and a poly(N-vinylpyrrolidone) polymer hydrogel, has a water content of at least about 70% by weight.

48. The material according to claim 47 wherein said water content is from about 85% to about 90% by weight.

49. A medical device fabricated from the material according to claim 1.

50. A catheter fabricated from the material according to claim 1.

51. A catheter balloon fabricated from the material according to claim 1.

52. A stent fabricated from the material according to claim 1.

53. A material bearing thereon a coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea polymer hydrogel, and a poly(N-vinylpyrrolidone) polymer hydrogel, said material and coating comprising:

a) a substrate, such that said substrate is a polymer selected from the group consisting of thermoplastic polyurethanes (TPU's), polyesters, nylon polymers, block copolymers of a polyether polymer and a polyester polymer, block copolymers of a polyether polymer and one selected from the group consisting of polyamides, polyimides, polyolefins, synthetic

hydrocarbon elastomers, and natural rubber; or that said substrate is a metal selected from the group consisting of stainless steel, titanium, alloys of steel, nickel, titanium, molybdenum, cobalt, and chromium, and nitinol (nickel-titanium alloy), and vitallium (cobalt-chromium alloy); said polymer or metal substrate having a surface with reactive chemical functional groups thereon, said reactive chemical functional groups being selected from the group (i-v) consisting of (i) amine-containing groups, which are selected from the group consisting of amino groups, amido groups, urethane groups, urea groups, and combinations thereof, when said substrate is a polymer, and which are amino-silane groups when said substrate is a metal; (ii) hydroxyl groups, (iii) carboxyl groups, (iv) carbonyl groups, and (v) combinations thereof, such that there are at least some amine-containing groups on said substrate surface;

b) a first coating, applied onto said substrate surface, said first coating containing a hydrophilic polyurethane-urea prepolymer intermediate, that is capable of forming a polyurethane-polyurea hydrogel-forming polymer, and that contains terminal isocyanate groups that are free to react with other species, said hydrophilic polyurethane-urea prepolymer intermediate being selected from the group consisting of a compound derived from a water-soluble polyether polyol or a copolyether polyol, and an organic polyisocyanate selected from the group consisting of aliphatic, cycloaliphatic, araliphatic, aromatic and heterocyclic polyisocyanates; such that at least some of said terminal isocyanate groups are reacted with and are covalently bonded to said reactive chemical functional groups on said substrate surface, forming covalent polyurea bonds therewith, resulting in the formation of a tie coat of a polyurethane-polyurea hydrogel-forming polymer, on said substrate surface, that tenaciously adheres to said substrate surface; wherein at least some of said terminal isocyanate groups of said polyurethane-urea prepolymer intermediate are present in said polyurethane-polyurea hydrogel-forming polymer of said tie coat, such that they remain free to react with other species; and

c) a second coating, applied onto said tie coat, said second coating containing an aqueous solution of a poly(N-vinylpyrrolidone) hydrogel-forming polymer;

wherein water of said aqueous solution of said poly(N-vinylpyrrolidone) hydrogel-forming polymer is bound with said polyurethane-polyurea hydrogel-forming polymer to form a first hydrogel of said commingled hydrogel, such that said first hydrogel of said commingled hydrogel is a polyurethane-polyurea polymer hydrogel;

wherein water of said aqueous solution of said poly(N-vinylpyrrolidone) hydrogel-forming polymer is bound with said poly(N-vinylpyrrolidone) hydrogel-forming polymer to form a second hydrogel of said commingled hydrogel, such that said second hydrogel of said commingled hydrogel is a poly(N-vinylpyrrolidone) polymer hydrogel; and

wherein said first hydrogel of said commingled hydrogel and said second hydrogel of said commingled hydrogel are commingled with one another, and form a composition selected from the group consisting of an interpolymer hydrogel network, a graft copolymer hydrogel, an association polymer hydrogel, and combinations thereof.

54. A material bearing thereon a coating of a dried, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea polymer hydrogel, and a poly(N-vinylpyrrolidone) polymer hydrogel, said dried hydrogel coating being reactivateable to a wet, slippery hydrogel, said material and said dried hydrogel coating comprising:

- a) a hydrophilic or hydrophilicized hydrophobic polymer substrate or a metal substrate, having a surface with reactive chemical functional groups thereon, at least some of which are amine-containing groups;
- b) a first coating, applied onto said substrate surface, said first coating containing a hydrophilic polyurethane-urea prepolymer intermediate, that is capable of forming a polyurethane-polyurea hydrogel-forming polymer, and that contains terminal isocyanate groups that are free to react with other species, such that at least some of said terminal isocyanate groups are reacted with and are covalently bonded to said reactive chemical functional groups on said substrate surface, forming covalent polyurea bonds therewith, resulting in the formation of a tie coat of a polyurethane-polyurea hydrogel-forming polymer, on said substrate surface, such that said polyurethane-polyurea hydrogel-forming polymer tenaciously adheres to said substrate surface;

and
wherein at least some of said terminal isocyanate groups of said polyurethane-urea prepolymer intermediate are present in said polyurethane-polyurea hydrogel-forming polymer such that they remain free to react with other species; and
c) a second coating, applied onto said tie coat, said second coating containing an aqueous solution of a poly(N-vinylpyrrolidone) hydrogel-forming polymer; such that a wet, slippery, tenaciously adhering, commingled hydrogel is formed on said tie coat upon the application of said second coating to said tie coat;
wherein water of said aqueous solution of said poly(N-vinylpyrrolidone) hydrogel-forming polymer is bound with said polyurethane-polyurea hydrogel-forming polymer to form a first hydrogel of said commingled hydrogel, such that said first hydrogel of said commingled hydrogel barrier coat is a polyurethane-polyurea polymer hydrogel;
wherein water of said aqueous solution of said poly(N-vinylpyrrolidone) hydrogel-forming polymer is bound with said poly(N-vinylpyrrolidone) hydrogel-forming polymer to form a second hydrogel of said commingled hydrogel, such that said second hydrogel of said commingled hydrogel is a poly(N-vinylpyrrolidone) polymer hydrogel;
wherein said polyurethane-polyurea polymer hydrogel of said commingled hydrogel and said poly(N-vinylpyrrolidone) polymer hydrogel of said commingled hydrogel are commingled with one another; and
wherein said wet, slippery, tenaciously adhering, commingled hydrogel is then dried to remove moisture therefrom, forming a dried, tenaciously adhering, commingled hydrogel coating on said substrate surface, such that said dried hydrogel coating is reactivatable to a wet, slippery, hydrogel coating by the re-exposure of said dried hydrogel coating to an aqueous fluid.

55. A two-part coating composition for a wet, slippery, tenaciously adhering, commingled hydrogel coating of a hydrophilic polyurethane-polyurea polymer hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel, for a hydrophilic or hydrophilicized hydrophobic polymer substrate or a metal substrate, that has a surface bearing reactive chemical functional groups thereon, said reactive chemical functional groups including at least some amine-containing groups, said composition comprising:

a) a first coating composition comprising a hydrophilic polyurethane-urea prepolymer intermediate, that is capable of forming a polyurethane-polyurea hydrogel-forming polymer, and that contains terminal isocyanate groups that are free to react with other species, such that at least some of said terminal isocyanate groups are capable of reacting with and covalently bonding to said reactive chemical functional groups on said substrate surface, to form covalent polyurea bonds therewith, resulting in the formation of a tie coat of a polyurethane-polyurea hydrogel-forming polymer, on said substrate surface, that tenaciously adheres to said substrate surface, to which said first coating composition is applied, with said hydrophilic polyurethane-urea prepolymer intermediate being derived from: a compound selected from the group consisting of a water-soluble polyether polyol and a water-soluble copolyether polyol; and an organic polyisocyanate selected from the group consisting of aliphatic, cycloaliphatic, araliphatic, aromatic and heterocyclic polyisocyanates; and
b) a second coating composition, for application onto said tie coat, said second coating composition comprising a poly(N-vinylpyrrolidone) hydrogel-forming polymer; with said second coating composition further comprising a moisture-containing, hydrogel-forming compound, that contains isocyanate-reactive functional groups, such that a barrier coat of a wet, slippery, tenaciously adhering, commingled hydrogel is formed upon the application of said second coating composition to said tie coat;

wherein said moisture of said hydrogel-forming compound is bound with said polyurethane-polyurea hydrogel-forming polymer of said tie coat to form a first hydrogel of said commingled hydrogel barrier coat, on said tie coat, such that said first hydrogel of said commingled hydrogel barrier coat is a polyurethane-polyurea polymer hydrogel;
wherein said isocyanate-reactive functional groups of said hydrogel-forming compound are reacted with and are covalently bonded to

at least some of said terminal isocyanate groups of said polyurethane-polyurea hydrogel-forming polymer of said tie coat, which were free to react therewith, thereby rendering said polyurethane-polyurea polymer hydrogel tenaciously adhering to said tie coat, and thus also tenaciously adhering to said substrate surface; wherein said moisture of said hydrogel-forming compound is bound with said poly(N-vinylpyrrolidone) hydrogel-forming polymer to form a second hydrogel of said commingled hydrogel barrier coat, such that said second hydrogel of said commingled hydrogel barrier coat is a poly(N-vinylpyrrolidone) polymer hydrogel; wherein said first hydrogel of said commingled hydrogel barrier coat and said second hydrogel of said commingled hydrogel barrier coat are commingled with one another, forming a composition selected from the group consisting of an interpolymer hydrogel network, a graft copolymer hydrogel, an association polymer hydrogel, and combinations thereof, such that said second hydrogel is thereby also rendered tenaciously adhering to said tie coat and thus also tenaciously adhering to said substrate surface; and wherein said commingled hydrogel barrier coat has a water content of at least 70% by weight.

56. An intermediate composition for forming a coating of a wet, slippery, tenaciously adhering, commingled hydrogel of a hydrophilic polyurethane-polyurea hydrogel and a poly(N-vinylpyrrolidone) polymer hydrogel, on a polymer or metal substrate material, said intermediate composition comprising:

a) a hydrophilic or hydrophilicized hydrophobic polymer substrate or a metal substrate, having a surface with reactive chemical functional groups thereon, said reactive chemical functional groups being selected from the group (i-v) consisting of (i) amine-containing groups, such that in the case of a polymer substrate, said amine-containing groups are selected from the group consisting of amino groups, amido groups, urethane groups, urea groups, and combinations thereof; and such that in the case of a metal substrate, said amine-containing groups are amino-silane groups; (ii) hydroxyl groups, (iii) carboxyl groups, (iv) carbonyl groups, and (v) combinations thereof, such that there are at least some amine-containing groups on said substrate surface; and b) a tie-coat, on said substrate surface, said tie coat comprising a hydrophilic prepolymer intermediate of a polyurethane-urea polymer or copolymer, containing terminal isocyanate groups that are free to react with other species, such that at least some of said terminal isocyanate groups are reacted with and are covalently bonded to said reactive chemical functional groups on said substrate surface, forming covalent polyurea bonds therewith, resulting in the formation of a polyurethane-polyurea hydrogel-forming polymer or copolymer, with said tie coat tenaciously adhering to said substrate surface; further such that at least some of said terminal isocyanate groups of said polyurethane polymer or copolymer are present in said polyurethane-polyurea hydrogel-forming polymer or copolymer, such that they remain available for reaction with a hydrogel-forming compound, that is applied to said tie coat and that contains isocyanate-reactive functional groups, said hydrogel-forming compound being selected from the group consisting of water, water-soluble amines, and combinations thereof, to form a barrier coat of a commingled hydrogel on said tie coat, which commingled hydrogel barrier coat tenaciously adheres to said tie coat; and

still further such that said polyurethane-polyurea polymer or copolymer is capable of commingling with a poly(N-vinylpyrrolidone) polymer, which is applied to said tie coat, such that said polyurethane-polyurea polymer or copolymer hydrogel of said commingled hydrogel barrier coat and said poly(N-vinylpyrrolidone) polymer hydrogel form a composition selected from the group consisting of an interpolymer hydrogel network, a graft copolymer hydrogel, an association polymer hydrogel, and combinations thereof, with said commingled hydrogel barrier coat tenaciously adhering to said tie coat and thus also tenaciously adhering to said substrate surface.

57. A polymeric plastic or rubber medical device coated with the coating composition according to claim 56.

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